

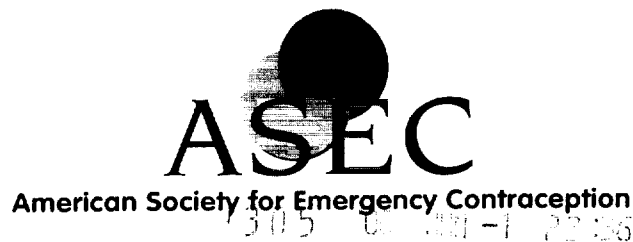
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May 26, 2000

Dockets Management Branch  
(HFA-305)  
Food and Drug Administration  
5630 Fishers lane, rm. 1061  
Rockville, MD 20852

RE: Docket No. 00N-1256: "FDA Regulation of OTC Drug Products Hearing"

To whom it may concern:

I am writing to inform you of my intent to offer oral comments at the June 28-29 meeting "FDA Regulation of OTC Drug Products Hearing." ASEC is interested in OTC status for oral contraceptives, with our interest driven by the special, short-term use of certain oral contraceptives as emergency therapy for women who have been raped or who are otherwise placed at risk of unwanted pregnancy.

My proposed testimony will cover the following points:

1. The World Health Organization has found that oral contraceptives used as emergency contraception (EC) have no contraindications and that they are safe and effective. They are also easy to use, not addictive, and not dangerous if taken incorrectly.
2. A study in the Lancet last year found that ECs work better the sooner they are started. For this reason, a prescription requirement significantly reduces women's chances to avoid unwanted pregnancy with this regimen.
3. Experience from Europe and also from Washington State shows that women use the therapy appropriately without mandatory doctor involvement.

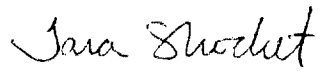
ASEC works to bring together organizations and individuals working on EC. We serve as a source of information on EC, and as watchdog for inaccurate or biased articles in the press related to EC. We also work to promulgate policies on EC and to support and disseminate the statements and guidelines of other organizations willing to endorse the method. I am the Deputy Director of ASEC.

00N-1256

APE 41

I request ten minutes during the hearing to elaborate on these issues.

Sincerely,

A handwritten signature in black ink, reading "Tara Shochet". The signature is written in a cursive, flowing style.

Tara Shochet, MPH  
Deputy Director